US ERA ARCHIVE DOCUMENT

Validation Sheet

Formulation: assumed to be 100% a.i.

Chemical Name: San 326 10 G

SAN 326 I = Diagna (REFE)

Validator: Ray Matheny

Date: 12 March 1979

Test Type: Avian Acute Oral LD50

Test I.D. #: Project No. 131 - 104

Citation: Fink, R. & J. Beavers. 1978. Acute Oral LD50 - Mallard Duck -

San 326 - Final Report - Submitted to Sandoz, Inc., Wildlife

International Ltd. (within Accession No. 097840).

Validation Category: Core

Result:

HENNIN

Species

Test

Confidence Limits

Mallard Duck

Oral LD50* 45 mg/K9 (36 - 56 mg/kg)

*Using the Probit Method, this test is validated at an LC50 of 45 mg/kg (34 - 57 mg/kg)

Validation Category Rationale: Satisfies core data requirements

Category Repairability/Rationale: N/A

Abstract: Standard test procedures were used. Mallard ducks from a production flock were randomly assigned to treatment groups at 22 weeks of age. Ten birds/each of five pens were used for the experimental and lab standard (dieldrin) groups. One pen of 10 birds served as control. Corn oil served as the carrier for the experimental and dieldrin material which was intubated directly into the crop via a stainless steel catheter. Body weights were recorded on days 3, 7 and the termination of the study. Temperature indoors was maintained at 70° - 80°F while the relative humidity ranged between 30% and 80%.

There were no mortalities in the negative control group. The dosage levels for SAN 326 were 25.1, 39.8, 63.1, 100 and 159 mg/kg, with mortalities of 1, 5, 6, 10 and 10, respectively. The dieldrin laboratory standard was tested at 14.7, 21.5, 31.6, 46.6, 68.2 with mortalities of 0, 2, 4, 5, & 10 respectively. Birds were observed for a total of 14 days.

With the experimental material @ 25.1 mg/kg dose level, some ataxia & loss of coordination was noted approximately 1 1/2 hours after dosing. After 5 hours, lower limb weakness & loss of coordination remained, with some birds exhibiting symptoms of wing droop, salivation and lacrimation. One bird succumbed on Day 1. By Day 2 all 25.1 dosed were asymptomatic.

Birds exposed to higher doses exhibited the classic toxic symptoms which included depression, reduced reaction to external stimuli, wing droop, high stepping, loss of coordination, prostrate posture, loss of righting reflex, lower limb rigidity, salivation, lacrimation, & some minor muscle fasiculation prior to death.

No consistent overt pathological changes were noted upon necropsy of birds dying during the study. Surviving birds, upon necropsy, showed no overt gross abnormalities. \$000 data 5 \$001 data 159, 100, 63.1, 39.8, 25.1 9002 data 10, 10, 10, 10, 10 9003 data 10, 10, 6, 5, 1 run

San 326 I Mallard duck LD50 3/12/79

79/03/12. 13.25.62. BASIC PROGRAM A78LC50

	*****	*****	******	***********	******
	CONC.	NUMBER	NUMBER	PERCENT	BINOMIAL :
		EXFOSED	DÉAD	DEAD	PROB. (PERCENT)
	159	10	10	100	9.76563E-2
	100	10	10	100	9.76563E-2
-	63.1	10	6 -	60.	37.6953
	39.8	10	5	50	62.3047
	25.1	10	- 1	10.	1.07422

THE BINOMIAL TEST SHOWS THAT 25.1 AND 100 CAN BE USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT CONFIDENCE LEVEL ASSOCIATED WITH THESE LIMITS IS 98.8281 FERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 39.8

-----RESULTS CALCULHTED USING THE PROBIT METHOD
ITERATIONS G H GOODNESS OF FIT PROBABILITY
5 .228744 1 .499817

SLOPE = 4.81109 95 PERCENT CONFIDENCE LIMITS = 2.51008 AND 7.11211

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